REMARKS

Status of the Claims

Applicant appreciates the Examiner's acknowledgement that Applicant's amendment and response filed 07/07/09 is acknowledged and has been entered. Applicant also appreciates the Examiner's acknowledgement that claims 1, 33 and 34 have been amended and that claim 14 has been cancelled leaving claims 1-4, 7, 8, 10-13, 32-34 and 38 pending and subject to examination.

Withdrawn Rejections

Applicant appreciates the Examiner's acknowledgement that all rejections not specifically reiterated in the most-recent Office Action have been withdrawn. Specifically, all rejections related to claim 14 have been rendered moot in light of it being cancelled without prejudice or disclaimer of the subject matter therein.

Rejection of Claims 32-34 under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 32-34 under 35 U.S.C. 112, first paragraph, for the reasons of record. Specifically the Examiner stated that the Applicant has not disclosed how one skilled in the art can establish with a high-level of predictability if the lipid phosphatase activity indicates a disease-caused alteration of lipid phosphatase or is due to obesity, age, temperature or disease.

Applicant respectfully again asserts that the instant specification provides sufficient examples and guidance related to this determination. Specifically, the Examiner is respectfully directed to Table 1 and paragraphs 0016 to 0018. Applicant also respectfully asserts that the changes associated with disease would be much greater than that associated with obesity, age, temperature or disease and that one skilled in the art would appreciate this distinction when reviewing assay results.

In light of the comments above, Applicant respectfully requests withdrawal of the rejection of claims 32-34 under 35 U.S.C. 112, first paragraph.

Rejection of Claims 1-4, 7, 8, 10-13, 32-34 and 38 under 35 U.S.C. 112, Second Paragraph

The Examiner rejected claims 1-4, 7, 8 and 10-13 under U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention for the reasons of record.

Previously, Applicant amended independent claims 1 and 32 to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Such amendments were made without prejudice or disclaimer of the subject matter therein and were made solely for the sake of moving prosecution forward. Support for the amendments can be found on p. 5, paragraph 26 and throughout the application.

Herein the Examiner has again stated that, "it is unclear how a change in concentration of the lipid product is determined," in claim 1 and p. 5 states that, "the assay can be any of a number of assay types, but is preferably a plate-based assay." The specification goes on to list enzyme linked immunosorbent assays, amplified luminescence proximity homogenous assays and fluorogenic assays, such as fluorescence polarization, fluorescence resonance energy transfer or time-resolved fluorescence resonance energy transfer. One skilled in the art would be familiar with each of these assay types.

The Examiner also ponders if a step in the claim is missing in light of the current claim language. Applicant respectfully requests a time to discuss this specific concern with the Examiner and, particularly, his concern in this regard.

The Examiner also asserts that Claim 1 is vague and indefinite because it is unclear, "how an actual change of the substrate lipid and lipid detector protein are determined absent a known baseline level for both elements." Applicant respectfully asserts that several methods of determining this are detailed in the Specification. For instance, please see paragraph 0053 wherein it states that, "a competition procedure can be performed using similar methodology." Please then refer to paragraph 0054 wherein it states, "[t]he results of the competition procedure can be determined by, for example, measuring absorbance (450 nm) for each of PI(4,5)P2 and PI(3,4,5)P3 at various pmol increments of competing PIP. Additionally, please refer to paragraph 0055 wherein it states , [a] standard curve in which increasing amounts of competitor is added to the assay is run alongside the enzyme reactions." These references are but a few that exemplify the manner in which one may

determine the change of a substrate lipid and lipid detector protein without a known baseline. One skilled in the art is familiar with competitive binding assays and also the generation of standard curves.

In light of the previous amendments made to claim 1 and the remarks above, Applicant again respectfully asserts that it now particularly points out and distinctly claims the subject matter the Applicant regards as its invention.

In light of the above comments, Applicant respectfully requests withdrawal of the rejection of claims 1-4, 7, 8, 10-13, 32-34 and 38 under U.S.C. 112, second paragraph.

Rejection of Claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a)

The Examiner rejected claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a) as being anticipated by Dowler for the reasons of record. Applicant respectfully traverses this rejection.

Initially, Applicant again respectfully asserts that the office action mischaracterizes the disclosures of Dowler. The reference teaches a method where a substrate lipid is incubated with an appropriate enzyme in the presence of a PH domain fused green fluorescent protein (see p. 131, lines 24-28). In no way does Dowler disclose exposing a lipid detector protein to a solution containing a substrate lipid **and** lipid phosphatase although Applicant does agree with the Examiner that it does disclose a method that "can comprise the substrate lipid in free solution (p. 130 and 132).

Specifically, Dowler does not disclose exposing a lipid detector protein to a solution containing a substrate lipid and lipid phosphatase or mention PI(4,5)P2, PI(5)P, or PI and specifically does not disclose binding of PI(3,4,5)P3. Additionally, Dowler does not disclose determining the levels of a substrate lipid, lipid detector protein and lipid product in solution.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-4, 7, 10, 11, 14, 32-34 and 38 under 35 U.S.C. 102(a).

Rejection of Claim 8 under 35 U.S.C. 103(a)

The Examiner has rejected claim 8 under 35 U.S.C. 103(a) over Dowler et al. in view of Goueli et al. (U.S. 6,720,162) ("Goueli") for the reasons of record.

As mentioned above and also previously, Applicant respectfully asserts that the office action mischaracterizes the disclosures of Dowler. The reference teaches a method where a substrate lipid is incubated with an appropriate enzyme in the presence of a PH domain fused green fluorescent protein (see p. 131, lines 24-28) Dowler does not disclose exposing a lipid detector protein to a solution containing a substrate lipid and lipid phosphatase. Additionally, in no way does Dowler disclose exposing a lipid detector protein to a solution containing a substrate lipid **and** lipid phosphatase although Applicant does agree with the Examiner that it does disclose a method that "can comprise the substrate lipid in free solution (p. 130 and 132).

Applicant also again asserts that the Examiner has mischaracterized Goueli. The Goueli reference describes lipid kinase and phosphatase assays where the lipid kinase and phosphatase assays where the lipid substrate is modified, i.e. biotinylated (or immobilized), and is detected radioactively which requires a separation step. The liquid phase assay in Goueli column 3 is also liquid during the enzymatic conversion, but detection still requires radioactivity and separation. Finally, Goueli also discloses the measurement of phosphatase activity by quantifying free phosphate. In contrast, the claimed lipid phosphatase assays always detect the lipid product, use nonbiotinylated/mobile substrates and do not require radioactivity or a separation step.

Therefore, Applicant respectfully again asserts that neither Dowler nor Goueli discloses all of the limitations of the claims at hand as required to make a case of obviousness. Additionally, the differences between the claimed invention and Goueli are of such a nature that one would not have had a reasonable expectation of success in using Goueli as a reference from which to learn how to conduct the claimed invention, making it unavailable as an obviousness reference.

In view of the foregoing remarks, Applicant respectfully requests withdrawal of the Examiner's rejections of claim 8 under 35 U.S.C. 103(a).

Rejection of Claims 12 and 13 under 35 U.S.C. 103(a)

The Examiner has rejected claims 12 and 13 under 35 U.S.C. 103(a) over Dowler et al. in view of Taylor (U.S. Analytical Biochemistry, 295, 122-126, 2001) ("Taylor") for the reasons of record.

As mentioned above and also previously, Applicant respectfully again asserts that the office action mischaracterizes the disclosures of Dowler for a variety of reasons. Along with the reasons stated above, Applicant also disagrees with the Examiner's statement that, "Dowler is generic with respect to the lipid phosphatases to be determined," as the assay of Dowler is very different from the assay of the present invention. One would not have had a reasonable expectation of success in using Dowler as a reference from which to learn how to practice the claimed invention, making it unavailable as an obviousness reference.

With that said, Applicant agrees with the Examiner's statement that, "Dowler differs from the instant invention in failing to teach the lipid phosphatase is myotubularin or PTEN." Applicant also agrees with the Examiner in that, "Dowler also fails to specifically state that the sample has additional lipids."

Therefore, neither Dowler nor Taylor discloses all of the limitations of the claims at hand as required to make a case of obviousness. Additionally, the differences between the claimed invention and the two references are of such a nature that one would not have had a reasonable expectation of success in using them from which to learn how to conduct the claimed invention, making it unavailable as an obviousness reference.

Provisional Rejection of Claims 1-4, 7, 8, 10-12 On Ground Of Non-Statutory Obviousness-Type Double Patenting

The Examiner has provisionally rejected claims 1-4, 7, 8, 10-12 and 14 on the ground of non-statutory obviousness-type double-patenting. Applicant will address this issue by filing a terminal disclaimer, should the need arise.

Concluding Remarks

In view of the foregoing, Applicant respectfully submits that all rejections under record have been overcome. Accordingly, Applicant believes that Claims 1-4, 7-8, 10-15, 32-34 and 38 are now in a condition for allowance.

Applicants representative below respectfully requests a telephonic interview to discuss the Examiner's concerns and the status of this case. The Examiner is welcome to contact Dr. Jennifer M. McCallum at the telephone number listed below at his convenience if he is amenable to this request..

Respectfully submitted,

4-28-10
Date

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